

REMARKS

Claims 1-18 and 20-33 are currently pending; claim 19 has been cancelled without prejudice or disclaimer. Claims 1, 4, 12-16, 20, 21, and 31 have been amended and claims 32 and 33 added to more clearly describe the present invention. Claims 12, 13, and 14 have been amended to correct clerical errors. Support for these amendments and the new claims is found throughout the specification, for example but not limited to, paragraphs 0035, 0040, and 0042 and Examples 2-4, 7-12, and 14.

Claim Objections

Claims 12, 13, and 14 were objected to and changes were suggested by the Examiner. See the Office Action at page 2. Applicants have amended claims 12, 13, and 14 to obviate these clerical and grammatical errors and respectfully request that the objections be withdrawn.

Rejection Under 35 USC § 112

Claims 4, 16, and 31 were rejected for allegedly being indefinite because they contained certain trademarks/trade names. See the Office Action at pages 2-3. Applicants respectfully disagree in that the skilled artisan would readily understand what is claimed. However, solely to expedite prosecution and not acquiescing to the Examiner's assertions, claims 4, 16, and 31 have been amended to remove the trademarks/trade names. Hence, the rejection is moot and Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S. C. §102

Claims 1-3, 14, 15, 17, and 19 were rejected under 35 USC § 102(b) as allegedly being anticipated by Gobbers et al. (J. Clin. Microbiol. 39(12): 4339-43, 2001), as evidenced by Jany et al. (FEBS Lett. 10(2): 139-44, 1986). The Examiner asserts that Gobbers et al. taught a method of isolating viral gDNA that employed proteinase K, guanidinium thiocyanate and a solid support. In order for a reference to anticipate a claimed invention, it must contain each element of the claimed invention. Since Gobbers et al. does not include a zwitterionic compound, the Examiner alleges that at physiological pH, proteinase K is a zwitterionic compound because it contains arginine, lysine, histidine, aspartate and glutamate residues, as depicted in Jany et al. Applicants respectfully assert that such an overly broad interpretation of zwitterionic compound would encompass virtually all proteins and is beyond what Applicants have described as zwitterionic compounds. See Specification, paragraphs 0040-0041. Thus, such an interpretation is neither reasonable nor consistent with the specification. However, solely to expedite prosecution and in no way acquiescing to the Examiner's assertions, claims 1 and 14 have been amended to recite "zwitterionic detergent". Claims 2 and 3 depend from claim 1 and claims 15 and 17 depend from claim 4. Claim 19 has been cancelled without prejudice or disclaimer. Thus, these amendments render the 102(b) rejection moot and Applicants respectfully request that the rejection be withdrawn.

Claims 14-17 have been rejected under 35 USC § 102(e) as allegedly being anticipated by Domanico et al. (US Published Application 20040180445;

“Domanico”). See Office Action at pages 4-5. Applicants respectfully disagree and traverse this rejection.

To anticipate a claim, every element of that claim must be found in a single reference. Domanico discusses certain putative methods and kits for purifying low molecular weight nucleic acid, e.g., plasmids and other heterologous extrachromosomal pieces of nucleic acid, from cellular debris. See, e.g., Domanico at paragraphs 0001, 0006, 0007, 0033, and 0035. Domanico describes the term purifying as separating low molecular weight nucleic acid from cellular debris, such as high molecular weight DNA, RNA, and protein; or separating RNA from cellular debris, including DNA. See Domanico at paragraph 0033. Claims 14 and 15, as amended, are directed to methods for obtaining nucleic acid, expressly including genomic DNA. Claims 16 and 17 depend on claim 15. Thus, Domanico fails to anticipate claims 14-17. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 1-24 are rejected as being unpatentable over Kuipers et al. in view of Domanico since allegedly it would have been obvious to use a zwitterionic detergent in the putative method of Kuipers. See Office Action at pages 5-7. The Examiner concedes that Kuipers does not disclose a zwitterionic detergent or a chaotrope. To overcome these deficiencies, the Examiner alleges, inter alia, that Domanico taught the use of zwitterionic detergents and chaotropes in a lysis buffers for DNA isolation procedures. The Examiner therefore concludes that it

would have been obvious to use a zwitterionic detergent and a chaotrope, as allegedly taught by Domanico, in the putative method of Kuipers. The Examiner further alleges that it would have been obvious to organize into a kit the elements of Kuipers as modified by Domanico. Applicants respectfully disagree and traverse this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2142.

As discussed above, Domanico discusses certain putative methods and kits for purifying low molecular weight nucleic acid, defined as “heterologous extrachromosomal pieces of nucleic acid, for example plasmids.” See Domanico at paragraph 0033; see also each and every figure in Domanico and each and every method and kit claim of Domanico. Additionally, Domanico expressly states that a low molecular weight nucleic acid is purified when it has been “separated from cellular debris, for example *high molecular weight DNA*, RNA, and protein.” See Domanico at paragraph 0035 (emphasis added). In marked contrast, Applicants inventive methods and kits provide high integrity nucleic

acid, *including but not limited to high molecular weight gDNA*. See Specification at paragraph 0042 (emphasis added) and Figures 3B and 5B. Thus, Applicants respectfully assert that the person of ordinary skill in the art would not be motivated to combine Domanico's method and kits for purifying low molecular weight DNA, such as plasmids, from high molecular weight DNA and other cellular debris with any other alleged method for the purpose of obtaining nucleic acid, including high molecular weight genomic DNA. Further, Applicants assert that the person of skill in the art would not have a reasonable expectation of successfully obtaining Applicants invention by combining the alleged teachings of Domanico and Kuipers. Since there is neither a motivation to combine Domanico's method with Kuipers nor a reasonable expectation that such combination would yield high molecular weight gDNA, Applicants assert that the Office has not established a prima facie case of obviousness. Thus, withdrawal of the rejection is respectfully requested.

Claims 21 and 25-31 are rejected as allegedly being unpatentable over Domanico. See Office Action at pages 7-8. As discussed above, Domanico alleged provides methods and kits for purifying low molecular weight nucleic acid, for example plasmid DNA separated from high molecular weight DNA, RNA and protein; or RNA separated from DNA. See, e.g., Domanico at paragraph 0035. Thus, Domanico neither teaches nor suggests Claim 21, as amended. Claims 25-31 depend on claim 21, either directly or indirectly. In light of the foregoing, reconsideration and withdrawal of the rejection is respectfully requested.

Obviousness-type Double Patenting Rejections

Claims 1-3, 5-12, 14, 15, 17-19, and 21-30 are rejected as allegedly being unpatentable over claims 1-64 of U.S. Patent No. 6,762,027 (the '027 patent). See Office Action at pages 8-10. According to the Examiner, the '027 claims are drawn to methods and kits for contacting whole tissue with a disrupting buffer comprising a protease and a cationic surfactant, substantially neutralizing the surfactant, and binding the nucleic acid to a solid phase. The Examiner concludes that it would have been obvious through routine optimization to assess various combinations of chaotropes and surfactants. Applicants respectfully disagree and traverse this rejection.

In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? If the answer is yes, then an "obviousness-type" nonstatutory double patenting rejection may be appropriate. Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent. See MPEP § 804 (emphasis in original). Applicants first note that claims 1-3, 5-12, 14, 15, 17-19, and 21-30 have been rejected, but the Examiner only specifically addresses "instant claims 5-7, 11, 12, and 15" (see first full paragraph on page 9 of the Office Action). Applicants also note that the Examiner's characterization of the methods claims of the '027 patent fails to include the limitation that "the whole tissue is not blood." See '027 claims 1 and 25. In contrast to the '027 method claims, the methods of the instant application clearly

include obtaining nucleic acid from blood, for example but not limited to Examples 2, 3, 4, 7, 8, 9, 10, 11, 12, 14 and corresponding figures. Additionally, Applicants have added new claims 32, dependent on claim 1, and 33, dependent on claim 14, to more clearly define the instant invention. Both of these new claims include the limitation that the biological sample of the corresponding independent claim comprises blood. Hence, the instant methods are patentably distinct from those claimed in the '027 patent. In light of the foregoing, Applicants respectfully disagree that the instant claims are rendered obvious by routine optimization of combinations chaotropes and surfactants.

With regard to the patentability of rejected kit claims 21-30, Applicants note that the independent kit claims of the '027 patent include a cationic surfactant while the independent kit claim of the instant application does not include a cationic surfactant. Compare claims 41 and 64 of the '027 patent with claim 21 of the instant application. Apparently in support of the Examiner's rejection of the claims 21-30 of the instant application, the Examiner contends that one portion of the '027 specification that he believes supports the '027 kit claims teaches washing solid supports comprising with ethanol and eluting the nucleic acid with an alkaline solution buffered with Tris and with a NaOH solution. See Office Action at pages 9 and 10. The Examiner then alleges that it would have been obvious to add wash and elution solutions to the '027 kits. While Applicants understand the Examiner's stated position with respect to the '027 claims, without taking a position either way on the accuracy of that position, Applicants respectfully assert that the Examiner has not addressed the basis for

rejecting the instant kit claims. Based on the foregoing, Applicants respectfully assert that this rejection is improper and request reconsideration and withdrawal of the rejection.

Claims 4, 13, 16, 20, and 31 are rejected as allegedly being unpatentable over the '027 patent in view of Domanico. See Office Action at pages 10-11. As discussed above, the amended claims are patentably distinct from those of the '027 patent at least because the '027 claims are directed to methods for macerating tissues, not blood. These deficiencies are not overcome by Domanico's alleged methods and kits for purifying low molecular weight nucleic acid, also discussed above. Applicants respectfully assert that this double-patenting rejection is improper. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

CONCLUSION

Applicants believe that the application is now in condition for allowance and respectfully request issuance of a Notice of Allowance. If the Examiner does not consider the application to be in condition for allowance, Applicants request that he call the undersigned at (760) 931-6676 to set up an interview.

PETITION FOR EXTENSION OF TIME AND FEE AUTHORIZATION

A petition for a 3-month extension of time is being transmitted concurrently. Should any extension of time and/or fee be necessary for timely submission of this paper, such extension of time is hereby requested. The Commissioner is authorized to charge **Deposit Account No. 01-2213 (5063)**.

Any deficiency or overpayment should be charged or credited to this deposit account.

Respectfully submitted,

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